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Thank you Secretary, and thank you members of the committee for bringing us together today. The victims of this devastating meningitis outbreak are present in our thoughts and we owe it to them to find answers and solutions.

I am a physician with experience working across the health care spectrum, from directing an innovative practice in Jamaica Plain, to serving as medical director of a network of long-term care facilities.

DPH's Bureau of Health Care Safety and Quality works to help improve access to quality emergency services, hospitals, community health centers, and nursing homes across the Commonwealth. The Bureau also has authority over the Division of Health Professions Licensure, which includes the Board of Registration in Pharmacy.

Today offers an opportunity for me to provide answers to questions surrounding the Board of Pharmacy. I will start by going through a chronology of events, complaints, and inspections that have occurred at NECC based on interviews with current and former staff, a review of thousands of pages of documents and emails, and more than a decade of reports.

The Massachusetts Board of Registration in Pharmacy's interaction with NECC began on July 16, 1998, when it obtained its initial license. On February 2, 1999, the Board received the first complaint against NECC, which alleged that the pharmacy had provided a prescriber with pre-printed prescriptions that specifically listed NECC medications. State law prohibits pre-printed prescriptions. Prescriptions are required to be patient-specific, and based upon the patient's diagnosis, medical history, allergies, tolerance, and the specific constellation of symptoms that the patient is presenting. This complaint was resolved in October 1999 with an informal reprimand letter, a non-disciplinary action.

In April 2002, working with the FDA, the Board visited NECC and obtained records related to a recent MedWatch report concerning betamethasone, a compounded steroid suppository. The FDA investigator met with Barry Cadden, owner of NECC, and conducted an inspection on April 9, concerning procedures, sterility and record keeping.

In October 2002, the Board initiated a joint investigation with the FDA at NECC related to the April 2002 betamethasone complaints as well as MedWatch reports

associated with the use of methylprednisolone acetate, the injectable steroid medication implicated in this current outbreak. The MedWatch reports pertained to two patients who received the steroid and experienced pain and headaches and were hospitalized with meningitis-like symptoms. Laboratory tests from these investigations identified subpotency of betamethasone and superpotency of methylprednisolone acetate. The FDA also noted contamination of one lot of methylprednisolone acetate with bacteria. These investigations continued into 2003.

Also in 2002, Board of Pharmacy member Karen Ryle convened a Task Force to study Board oversight of the compounding pharmacy industry. Barry Cadden served on this Task Force, which met for nearly two years. The Task Force discussed proposals to change regulations around compounding, but records do not show whether formal recommendations were made, and the Board did not adopt new regulations.

In February 2004, the Board conducted a follow up inspection of NECC and noted that all deficiencies surrounding sterility, safety, quality and procedures from the 2002-2003 investigations had been resolved. Just weeks later, however, the Board received a complaint, from a pharmacist in Wisconsin, expressing concerns with the safety of a topical anesthetic product. The complaint alleged that NECC advised the pharmacy to unlawfully use a staff member's name rather than an individual patient's name in filling a prescription. The Board then in place resolved this complaint with a disciplinary warning letter on September 30, 2004.

Based on this series of investigations, in September 2004, the Board voted unanimously to sanction NECC with a reprimand, a three-year probation, and a requirement that Barry Cadden obtain additional training in sterile compounding. NECC objected to these sanctions, but the Board reaffirmed this approach through an additional unanimous vote on November 23, 2004.

More than a year later, on January 10, 2006, NECC entered into a non-disciplinary consent agreement with the Board that was significantly weaker than the earlier version. The signed consent agreement stipulated a one-year probation to be stayed with the condition that NECC hire an independent evaluator. The Board's staff identified Pharmaceutical Systems, Inc. (PSI) as the evaluator to conduct inspections of NECC's compounding practices.

Despite interviews with Board and staff members involved with these decisions and a thorough review of the limited records retained from this period, troubling questions remain about what influenced the more lenient consent agreement resolution, given NECC's track record. I will not be satisfied until we know the full story behind this decision.

What we know now is that from January to April 2006, the independent evaluator PSI conducted an assessment of NECC's compliance with United States

Pharmacopeia Standards, and oversaw development of policies and procedures. PSI also issued recommendations for process improvement and provided training for NECC staff. An April 7, 2006 report from PSI described NECC's compliance with the evaluation.

Our investigation has revealed that in late April 2006, some Board of Pharmacy and Health Professions Licensure staff, including the Board's executive director and legal counsel, learned that PSI executives were convicted of federal crimes related to defrauding the FDA and selling unapproved sterilization equipment to hospitals. However, we have found no evidence to indicate that the Executive Director or staff attorney of the Board provided this crucial in formation to the Board. Nor did they see fit to send inspectors back to NECC in 2006 to determine if they were fulfilling the requirements of the corrective action plan.

In May 2006, the Board voted to affirm that NECC was in compliance with the terms of the consent agreement, thus accepting PSI's findings in overseeing NECC's compliance.

Consistent with Board policy at the time, which was to inspect pharmacies only upon a change in licensure status or upon receipt of a complaint, the next time a Board investigator returned to the pharmacy was five years later on May 24, 2011 to inspect NECC following its renovation and expansion. This inspection included a full review of the facility space, operations, sterility protocols, and compliance with United States Pharmacopeia among other factors. The inspector found no evidence to suggest that NECC was violating patient-specific prescription requirements, and no deficiencies were cited.

In March 2012, the Board received a complaint pertaining to an insufficiently potent eye anesthetic distributed by NECC. This complaint focused on the potency of the medication but did not reference sterility concerns. This investigation continues.

In July 2012, some of the same staff members who failed to inform the Board of the issues surrounding PSI received a report from the Colorado Board of Pharmacy documenting violations of Colorado and Massachusetts pharmacy laws. The information provided to the Board executive director and legal counsel by Colorado showed that NECC had distributed bulk shipments of drugs to many hospitals in that state between 2010 and 2012 without patient –specific prescriptions, in violation of NECC's Colorado and Massachusetts licenses. The Colorado Board of Pharmacy issued a cease and desist order to stop NECC from engaging in the unlawful distribution of prescription drugs in the state in April 2011. Colorado informed the FDA of the adverse action, and provided them with the report, supporting evidence, and copy of the order. However, there is no record of Colorado providing similar notice to the Board or DPH.

Colorado contacted Board staff in July 2012 because NECC was violating the April 2011 cease and desist order by continuing to prepare and dispense bulk shipments without patient-specific prescriptions. However, after receiving the July report and the cease and desist order, both the executive director and legal counsel failed to order an investigation, inform the Board of the complaint, or take any other action on the Colorado complaint.

This lack of action is even more appalling in the context of the sequence of events regarding the NECC meningitis outbreak. The first two lots of contaminated methylprednisolone acetate linked to the meningitis outbreak were prepared in May and June of 2012. The Colorado report was received two weeks prior to the production and shipping of the third lot of contaminated vials, which were prepared in August. Though issues of contamination with NECC products were not included in the Colorado report, given NECC's history and the evidence from Colorado that the company was violating Massachusetts pharmacy regulations, prompt action was warranted.

The individuals responsible for this failure to act have been removed from their jobs.

As Secretary Bigby said, poor judgment, missed opportunities and lack of appropriate action allowed NECC to continue on this troubling path, and we have taken actions to ensure this never happens again.

We are focused on creating a culture of accountability. As we move forward, we must take all opportunities, state and federal, to ensure that proper oversight and benchmarks are put in place so this type of tragedy cannot happen again. Clearly there is opportunity for improving alignment with our federal partners, and opportunity to tighten state oversight of this industry. We are well along that path and we won't stop until all of these critical changes are in place.

And finally, per your request, I have included as an addendum information on the Bureau of Health Care Safety and Quality.

Thank you.